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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,045

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Yasuo Suda

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MORRISON & FOERSTER LLP
425 MARKET STREET
SAN FRANCISCO, CA 94105-2482

EXAMINER

HAQ, SHAFIQUL

ART UNIT

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DELIVERY MODE

11/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,045	Applicant(s) SUDA, YASUO	
	Examiner SHAFIQL HAQ	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

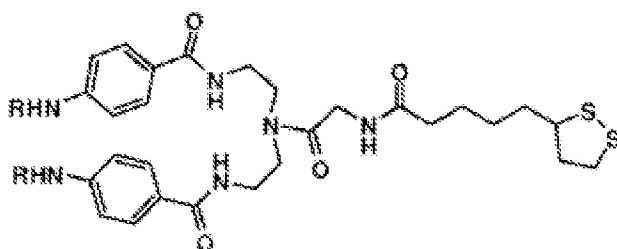
- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/16/07, 5/27/09 & 10/14/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Election/Restrictions

1. Applicants' election of a single species for a "linker compound", a "sugar chain" and an "aromatic amino group" in response to election of species requirement of 7/29/09 is acknowledged. As set forth in the restriction requirement and an election of single species of a linker compound, the invention will encompass all compounds that fall within the scope of the claim is as follows:

The linker compound having the formula:



, wherein R is a sugar chain.

As a result of the election and the corresponding scope of the compound identified, claims 3 and 5 and remaining subject matter of claims 1, 2, 4 and 6-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected inventions. The withdrawn subject matter of the claims (i.e. other structurally divergent linker compound) is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct there from. Examiner suggests that the non-elected claims cited supra and non-elected subject matter be canceled in response to this Office action to expedite prosecution.

2. Claims 1-2, 4 and 6-10 are examined on merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-2, 4 and 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 1 recites "X is a structure comprising one, two or three hydrocarbon derivative chains which have an aromatic amino group at an end and may have a carbon-nitrogen bond in the main chain". It is unclear what is intended to encompass by "hydrocarbon derivative chains". Hydrocarbon chain derivatized with what? The arrangement of the one, two or three hydrocarbon derivative chains are also vague and indefinite as it is not clear how are the two or three hydrocarbon derivative chains are linked to each other, linked linearly or linked to the same atom and therefore, the structural composition of "X" is unclear. Further, the term "aromatic amino group" is confusing because it is unclear whether aromatic amino group is intended to describe an aromatic structure having amino group as part of the aromatic structure or the amino group is a substitution on the aromatic structure.
6. Claim 1 recites "Y is a sulfur atom" in line 10. When Y is simple sulfur atom, the simple sulfur atom does not satisfy valency requirement. Are applicants intended to describe thiol group? Further, the claim recites "a hydrocarbon structure containing a sulfur atom". The recitation incorporates single sulfur atom containing 3, 4, 5 ----

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ring containing structures or two linear chain hydrocarbon structures linked by a single molecule of sulfur atom. It is unclear as to whether all these structures are intended to encompass in the structure of the compound by the recitation? There are written description issues which have not been applied at this time, but Applicants should amend the claim with caution in order to avoid any new matter or written description issues.

7. Claim 1 recites “the sugar having a reducing end and being bonded to the linker compound through the aromatic amino group” in last two lines. It is unclear as to whether the sugar is linked to aromatic amino group through the amino group of the aromatic amino group or to carbon atom of the aromatic structure of the aromatic amino group.
8. With regard to claims 4 and 7, the bond when m^4 and $m^5=0$ is unclear because when m^4 and $m^5=0$, NH of the $-C(O)NH$ would be linked to N of the $NC(O)-$ through a single bond and it is unclear what kind of linkage would be encompassed by this situation.
9. With respect to claims 10, the term “supporter” is not a common terminology. Applicants are advised to replace the term with “support”.
10. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: clear steps for analyzing intermolecular interaction.

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11. Claim 9 provides for using the ligand of claim 8 for protein analysis, but since the claims do not set forth any positive steps how the use is practiced, it is unclear what method/process steps applicant is intending to encompass for the use of the ligand of claim 8. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. Claims 1-2 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Arano *et al* (Tentative lecture proceedings II in the 79th Spring Meeting, Chemical society of Japan 2001).

Arano *et al* disclose a linker compound linked to a sugar (see the abstract) that reads on the compound of claim 1 of instant application when in the compound Y=hydrocarbon structure containing a sulfur atom, p and q=0, Z=straight chain structure comprising carbon-carbon bond or carbon oxygen bond and X=a structure comprising one hydrocarbon derivative chain which have an aromatic amino group at an end and may have a carbon nitrogen bond in the main chain and a sugar is bonded to the linker compound through the aromatic amino group.

With regard to claim 2, the linker compound of Arano *et al* comprises a hydrocarbon structure having a S-S bond.

With regard to claim 6, the linker compound of Arano *et al* comprises CH₂ groups.

With regard to claim 7, Arano *et al* disclose a method for producing a ligand conjugate comprising reacting sugar with the linker compound by reductive amination (see the flow chart).

With regard to claims 8 and 9, Arano *et al* teach immobilizing the linker ligand conjugate to a solid support for protein analysis (see abstract).

16. Claims 1-2 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Arano *et al* (Chemical society of Japan 2002, page 137, 82th Fall Meeting).

Arano *et al* disclose a linker compound linked to a sugar (see the abstract) that reads on the compound of claim 1 of instant application when in the compound Y=hydrocarbon structure containing a sulfur atom, p and q=0 or 1, Z=straight chain structure comprising carbon-carbon bond or carbon oxygen bond and X=a structure comprising three hydrocarbon derivative chain which have an aromatic amino group at an end and may have a carbon nitrogen bond in the main chain and a sugar is bonded to the linker compound through the aromatic amino group.

With regard to claim 2, the linker compound of Arano *et al* comprises a hydrocarbon structure having a S-S bond.

With regard to claim 6, the linker compound of Arano *et al* comprises CH₂ groups.

With regard to claim 7, Arano *et al* disclose a method for producing a ligand conjugate comprising reacting sugar with the linker compound by reductive amination (see the flow chart).

With regard to claims 8 and 9, Arano *et al* teach immobilizing the linker ligand conjugate to a solid support for protein analysis (see abstract).

17. Claims 1-2 and 6-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Suda *et al* (JP 2003-083969).

Suda *et al* disclose a linker compound linked to a sugar (see the abstract) that reads on the compound of claim 1 of instant application when in the compound Y=hydrocarbon structure containing a sulfur atom, p and q=0, Z=straight chain structure comprising carbon-carbon bond or carbon oxygen bond and X=a structure

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comprising one hydrocarbon derivative chain which have an aromatic amino group at an end and may have a carbon nitrogen bond in the main chain and a sugar is bonded to the linker compound through the aromatic amino group.

With regard to claim 2, the linker compound of Suda *et al* comprises a hydrocarbon structure having a S-S bond.

With regard to claim 6, the linker compound of Suda *et al* comprises CH₂ groups.

With regard to claim 7, Suda *et al* disclose a method for producing a ligand conjugate comprising reacting sugar with the linker compound by reductive amination (see the flow chart).

With regard to claims 8 and 9, Suda *et al* teach immobilizing the linker ligand conjugate to a solid support for protein analysis (see abstract).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being Unpatentable over Suda *et al* (JP 2003-083969).

Suda *et al* disclose a linker compound wherein a branched structure containing two hydrocarbon derivative chain having a terminal aromatic amino group is bonded to a biotin terminal (see compound 2). Sugars are then linked to amino group

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attached to benzene ring by reductive amination reaction to prepare compound 5 ligand (paragraph [0120]). Suda *et al* also disclose that by taking advantage of biotin-streptavidin affinity, compound 5 was arranged on a surface of a sensor chip having streptoavidin immobilized thereon. A surface plasmon resonance measurement method for detecting interaction of saccharides with the ligand is also disclosed.

Suda *et al* disclose dithilane group attached to one hydrocarbon derivative chain having a terminal aromatic amino group but do not disclose dithiolane group attached to the two hydrocarbon derivative chain having a terminal aromatic amino group.

Nelson *et al.* disclose a ligand comprising dithiolane group for preparing self-assembled monolayer on metal (e.g. gold) surfaces. The composition provides a highly versatile tethers suitable for immobilization on a metal backbone. Nelson *et al.* disclose several advantage of using 1,2 dithiolane (i.e. tethering group containing cyclic S-S-) in columns 4-6. One particular advantage is, when bound to metal surface, a 1,2-dithiolane composition of the invention is chemically stable in a wide variety of hostile media and conditions (column 5, lines 1-4). Another advantage cited is that 1,2-dithiolane is thioctic acid, d-thioctic acid (i.e. lipoic acid as disclosed in claim 17 of present application) or derivatives and d-thioctic acid is a natural substance found in mammals and thus are physiologically compatible.

Therefore, given the above fact the 1,2 dithiolane (i.e. tethering group containing cyclic S-S-) is advantageous for its stable association with gold surface and is

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physiologically compatible (Nelson *et al*) and since Suda *et al* also disclose dithiolane attached to one carbon derivative chain for attachment to gold surface, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute biotin anchoring group with cyclic –S-S- group (e.g. 1,2-dithiolane, specially lipoic acid) in the tethering residue of Suda *et al*, with the expectation of obtaining sensor chip stably associated with the linker compound with a reasonable expectation of success.

With regard to analysis of bound protein by mass spectrometric analysis of bound protein of claim 10, since Suda *et al* teach the method of capturing analytes on a solid support, the use of a particular know method (as for example, SPR analysis, immunoassay analysis or mass spectrometric method of analysis of bound protein) for analysis of the bound protein is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a) absent unexpected result.

20. Claims 1-2, 4 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi *et al* (Tentative Lecture Proceeding, Chemical Society of Japan 2001) in view Sumida *et al* (JP 2002-80488 A) and Tomalia *et al* (US 5,714,166) and further in view of Nelson *et la* (US 6,756,345 B2).

Hayashi *et al.* disclose a linker compound wherein a branched structure containing two hydrocarbon derivative chain having a terminal aromatic amino group is bonded to a biotin terminal (see compound 1). Sugars are then linked to amino group attached to benzene ring by reductive amination reaction to prepare

compound 2 ligand. Hayashi *et al* also disclose that by taking advantage of biotin-streptavidin affinity, compound 2 was arranged on a surface of a sensor chip having streptavidin immobilized thereon. A surface plasmon resonance measurement method for detecting interaction of saccharides with the ligand is also disclosed.

Hayashi *et al* do not disclose using dithiolane anchoring group for attaching the ligand to solid surface such as for attaching to sensor chip surface. However, use of dithiolane for anchoring ligands on solid surface is well known in the art of biosensors.

Nelson *et al.* disclose a ligand comprising dithiolane group for preparing self-assembled monolayer on metal (e.g. gold) surfaces. The composition provides a highly versatile tethers suitable for immobilization on a metal backbone. Nelson *et al.* disclose several advantage of using 1,2 dithiolane (i.e. tethering group containing cyclic S-S-) in columns 4-6. One particular advantage is, when bound to metal surface, a 1,2-dithiolane composition of the invention is chemically stable in a wide variety of hostile media and conditions (column 5, lines 1-4). Another advantage cited is that 1,2-dithiolane is thioctic acid, d-thioctic acid (i.e. lipoic acid as disclosed in claim 17 of present application) or derivatives and d-thioctic acid is a natural substance found in mammals and thus are physiologically compatible.

Therefore, given the above fact the 1,2 dithiolane (i.e. tethering group containing cyclic S-S-) is advantageous for its stable association with gold surface and is physiologically compatible, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute biotin anchoring group with

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cyclic –S-S- group (e.g. 1,2-dithiolane, specially lipoic acid) in the tethering residue of Hayashi et al, with the expectation of obtaining sensor chip stably associated with the linker compound with a reasonable expectation of success.

With regard to analysis of bound protein by mass spectrometric analysis of bound protein of claim 10, since Suda *et al* teach the method of capturing analytes on a solid support, the use of a particular know method (as for example, SPR analysis, immunoassay analysis or mass spectrometric method of analysis of bound protein) for analysis of the bound protein is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a) absent unexpected result.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-2, 4 and 6-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of US patent 7,183,067 in view of Nelson *et al* (US 6,756,345 B2).

US patent '345 discloses a linker compound which is similar to the linker compounds of instant application differing only by anchoring group that attaches the linker compound to a solid surface. Copending application disclose biotin as anchoring group whereas the anchoring group in the compounds of present application is dithiolane group of thioctic acid.

Nelson *et al.* disclose a ligand comprising dithiolane group for preparing self-assembled monolayer on metal (e.g. gold) surfaces. The composition provides a highly versatile tethers suitable for immobilization on a metal backbone. Nelson *et al.* disclose several advantage of using 1,2 dithiolane (i.e. tethering group containing cyclic S-S-) in columns 4-6. One particular advantage is, when bound to metal surface, a 1,2-dithiolane composition of the invention is chemically stable in a wide variety of hostile media and conditions (column 5, lines 1-4). Another advantage cited is that 1,2-dithiolane is thioctic acid, d-thioctic acid (i.e. lipoic acid as disclosed in claim 17 of present application) or derivatives and d-thioctic acid is a natural substance found in mammals and thus are physiologically compatible.

Therefore, given the above fact the 1,2 dithiolane (i.e. tethering group containing cyclic S-S-) is advantageous for its stable association with gold surface and is physiologically compatible, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute biotin anchoring group with

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cyclic –S-S- group (e.g. 1,2-dithiolane, specially lipoic acid) in the tethering residue in the compounds of copending application, with the expectation of obtaining sensor chip stably associated with the linker compound with a reasonable expectation of success.

23. Claims 1-2, 4 and 6-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of US patent 7,320,867.

Although the conflicting claims are not identical, they are not patentably distinct from each other because US patent '867 discloses a linker compound which is similar to or are drawn to structures that are structural homolog of the linker compounds of instant application.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR

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only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/
Primary Examiner, Art Unit 1641